

US App. No. 10/686,970  
Response to 6/14/06 Office Action

RECEIVED  
CENTRAL FAX CENTER  
SEP 14 2006

### REMARKS

Claims 25 and 28 have been amended to further clarify the claim language. Claims 34-38 have been added to claim further embodiments of the present invention. Support for new claims 34 and 35 is found on page 10, lines 1-6 and in the last sentence of that page. Support for claims 36 and 37 is found on page 11, fourth paragraph through page 12, line 3. Support for new claim 38 is found on page 6, second paragraph, first sentence. The amendments do not introduce any new matter.

The present claims are directed to a test strip, a system comprising that test strip, and a method for detecting and quantitating an analyte present in a sample applied to the test strip. More particularly, the system utilizes a test strip that contains two separate reactive agents: 1) a control substance and 2) a reagent, wherein the control substance reacts with the sample matrix (e.g. the solvent) and the reagent reacts with the analyte to be detected. Upon contact of the sample with the control substance and the analyte, detectable signals will be generated by the control substance and the analyte that are indicative of the respective sample fluid volume and analyte concentration. Thus by measuring the signal produced by the control substance, a determination can be made as to whether a sufficient amount of sample has been applied to the test strip or whether the test strip has been filled with less than the optimal amount (underdosed). In the latter case the amount of analyte signal detected can be adjusted to compensate for the underdosing to allow for an accurate determination of the analyte concentration in the sample.

Claim 19 stands rejected under 35 USC § 102(e) as being anticipated by Petrich et al. (US Patent No. 6,363,890). Applicants respectfully traverse.

Petrich et al disclose a test strip and method for detecting an analyte based on an interaction of a reagent with the analyte that produces a detectable signal in proportion to the

US App. No. 10/686,970  
Response to 6/14/06 Office Action

amount of analyte present. Petrich also suggests that the amount of secondary light emitted from the circumferential surface of the test strip is characteristic of the liquid taken up by absorption in the test area, and thus may provide an indication of the uptake of a liquid by the absorbent test layer. However, Petrich fails to teach a step of determining the amount of the sample placed on the test element based on an interaction between a control substance disposed on the test element and a sample matrix of the sample. Applicants note that the specification specifically defines the term "sample matrix" on page 11, first sentence as follows: "Within the scope of the invention a sample matrix means all sample components which are not referred to as analyte and are present in adequate amounts in the sample." The only interaction that Petrich discloses is one between the analyte and a reagent.

Petrich's suggestion that the measurement of secondary light emitted by the circumferential surface of their device provides information regarding sample uptake simply does not anticipate the presently claimed method. Petrich does not teach a method that uses a second reactive agent (i.e., control substance) on their test strip that interacts with the sample matrix, resulting in the production of a modified control sample that produces a signal in proportion to the amount of sample present on the test strip.

To anticipate a reference must teach every step of the claimed process. Petrich fails to teach a step of interacting a control substance (already present on the test strip and distinct from the reagent used to detect the analyte) with the sample matrix to produce a detectable signal that is correlated with the amount of sample present on the test strip. Accordingly, applicants respectfully request the withdrawal of the rejection of claim 19 as being anticipated by Petrich.

US App. No. 10/686,970  
Response to 6/14/06 Office Action

Claims 19-22, 23-25, 26-27, 28-31 and 32-33 stand rejected under 35 USC § 102(e) as being anticipated by Modzelewski et al. (US Patent No. 6,541,266). Applicants respectfully traverse.

Modzelewski et al. discloses a method of measuring an analyte, such as glucose, in a fluid sample, such as whole blood, by a reflectance reading device. The novel element of their disclosed method relates to making periodic intermediate calculations of analyte levels to determine when an analytical reaction has reached an end point. Such multiple measurements allow for the calculation of the final, actual glucose concentration present in the sample. The Modzelewski reference is devoid of any teaching or suggestion regarding measuring the amount of sample loaded onto the test strip to determine if the test strip was underdosed. Similar to Petrich, the Modzelewski test strip contains only one reactive agent that interacts with an analyte present in a sample to produce a detectable signal that is indicative of the presence of the analyte. There is nothing in Modzelewski that addresses the issue of determining whether the amount of sample loaded onto the test strip was sufficient to provide an accurate reading.

The Examiner has made reference to column 12, lines 4-16 of Modzelewski as providing a teaching for correcting the detected analyte concentration using linear extrapolation. However, contrary to the Examiner's assertions, this correction relates to an extrapolation based on the slope of the curve generated by the calculation of intermediate glucose values, not the volume of the sample (see column 11, lines 45-58). There is simply no suggestion in Modzelewski that the determined glucose values would need to be adjusted based on an underdosage of the test strip.

Applicant's compositions and methods allow for the independent detection of analyte and measurement of sample volume on the test strip. Applicants are able to do this because the test strip contains both a reagent that interacts with the analyte to be detected, as well as a separate

US App. No. 10/686,970  
Response to 6/14/06 Office Action

control substance that indicates the amount of sample present on the test strip. Modzelewski fails to teach the inclusion of this second "control substance" that interacts with the sample matrix (e.g., water) to produce a detectable signal indicative of the amount of loaded sample. Accordingly, applicants respectfully request the withdrawal of the rejection of claims 19-23 as being anticipated by Modzelewski.

The cited Petrich and Modzelewski references each teach a system containing a single reactive agent that interacts with an analyte present in a sample to provide a detectable signal for measuring the amount of analyte present. Those references fail to teach the inclusion of a second reactive agent on the test strip, wherein the second reactive agent interacts with the sample matrix (e.g., water) to produce a detectable signal indicative of the amount of loaded sample. Accordingly, the cited references fail to teach applicants' claimed device and method that allows one determine whether or not a sufficient quantity of sample has been added to the test strip, as well as determine the concentration of the analyte in the sample.

Applicants believe the claimed invention is patentably distinct from the cited references and respectfully request allowance of the claims, and passage of the application to issuance. If any further discussion of this matter would speed prosecution of this application, the Examiner is invited to call the undersigned at (434) 220-2866.

Respectfully presented,



John P. Breen  
Registration No. 38,833  
Attorney for Applicants

(317) 261-7940  
Indianapolis, Indiana 46204